

Food and Drug Administration, HHS

§ 524.2620

weeks of age and older, and cats 8 weeks of age and older.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 37401, July 12, 1999, as amended at 64 FR 48707, Sept. 8, 1999; 65 FR 45282, July 21, 2000; 74 FR 19878, Apr. 30, 2009]

§ 524.2101 Selenium disulfide suspension.

(a) *Specifications.* The product contains 0.9-percent weight in weight (w/w) selenium disulfide (1-percent weight in volume (w/v)).

(b) *Sponsors.* See Nos. 000061, 017135, and 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use on dogs—(1) Indications for use.* For use as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and nonspecific dermatoses.

(2) *Amount.* One to 2 ounces per application.

(3) *Limitations.* Use carefully around scrotum and eyes, covering scrotum with petrolatum. Allow the shampoo to remain for 5 to 15 minutes before thorough rinsing. Repeat treatment once or twice a week. If conditions persist or if rash or irritation develops, discontinue use and consult a veterinarian.

[47 FR 53351, Nov. 26, 1982, as amended at 48 FR 32762, July 19, 1983; 54 FR 36962, Sept. 6, 1989; 56 FR 9623, Mar. 7, 1991; 58 FR 41025, Aug. 2, 1993; 63 FR 26981, May 15, 1998; 70 FR 50183, Aug. 26, 2005]

§ 524.2350 Tolnaftate cream.

(a) *Specifications.* The drug contains 1 percent tolnaftate (2-naphthyl-*N*-methyl-*N*-(3-tolyl) thionocarbamate) in an anhydrous cream base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypsum* in dogs and cats.

(2) A small amount of the cream is applied to the affected areas once or twice a day for 2 to 4 weeks. The areas to be treated are first cleared of exudate and the hair clipped if the areas are not already denuded. The cream is massaged into each lesion and immediate surrounding area until the cream is no longer visible.

(3) If no response is seen after 2 weeks of treatment with the drug the diagnosis should be reviewed.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 29289, July 7, 1978, as amended at 52 FR 7833, Mar. 13, 1987]

§ 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 4916, Jan. 31, 2003, as amended at 78 FR 17868, Mar. 25, 2013]

§ 524.2483 Triamcinolone cream.

(a) *Specifications.* The vanishing cream contains 0.1 percent triamcinolone acetonide.

(b) *Sponsor.* See Nos. 000010 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Rub into affected areas two to four times daily for 4 to 10 days.

(2) *Indications for use.* For topical treatment of allergic dermatitis and summer eczema.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006, as amended at 73 FR 79318, Dec. 29, 2008. Redesignated and amended at 75 FR 10168, Mar. 5, 2010; 77 FR 60302, Oct. 3, 2012]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a)(1) *Specifications.* The drug is a liquid for direct application or an aerosol preparation formulated so that each

gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) *Sponsor*. See No. 051079 in § 510.600(c) of this chapter.

(b)(1) *Specifications*. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*. The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 56307, Dec. 28, 1976; 50 FR 9800, Mar. 12, 1985; 54 FR 25565, June 16, 1989; 56 FR 37474, Aug. 7, 1991; 66 FR 46369, Sept. 5, 2001; 72 FR 36595, July 5, 2007]

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec.

526.88 Amoxicillin trihydrate for intramammary infusion.
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 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.
 526.1810 Pirlimycin.

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§ 526.88 Amoxicillin trihydrate for intramammary infusion.

(a) *Specifications*. Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use—Lactating cows—*(1) *Amount*. One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.

(2) *Indications for use*. For the treatment of subclinical infectious bovine mastitis due to *Streptococcus agalactiae* and *Staphylococcus aureus* (penicillin sensitive).

(3) *Limitations*. Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.313 Ceftiofur.

(a) *Specifications*. Each single-use, 10-milliliter syringe of ceftiofur hydrochloride suspension contains 125 milligrams (mg) or 500 mg ceftiofur equivalents.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use in cattle—*(1) *Lactating cows—*(i) *Amount*. Infuse 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) *Indications for use*. For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*.